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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,267	01/17/2002	Jean-Louis Ruelle	BM45351	2480

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	PAPER NUMBER
1645	9

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/889,267	RUELLE, JEAN-LOUIS	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-49* is/are pending in the application.

4a) Of the above claim(s) *26, 28, 30, 33, 34, 35, 36 – 42, 45 and 47-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25, 27, 29, 31, 32, 43- 44 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *25-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's response to restriction in Paper No. 8 (12/9/02) is acknowledged. Claims 25-49 are pending in the application.

Election

2. Applicant's election Group I, claims 25, 27, 29, 31, 32, 35, 43- 44 and 46 with respect to SEQID.NO: 2, drawn to polypeptide, fusion polypeptide, vaccine and a method of inducing immune response in Paper No. 8 is acknowledged.

3. The traversal is on the ground(s) that SEQ.ID.NO: 2 and 4 are similar, share a common structure, a significant structural element, isolated from strains of Neisseria meningitidis and brings the examiner attention to PCT Rule 13.2.

Applicant states group I, i.e., Inventions SEQ.ID.NO: 2 and 4 are linked by the common generic "special technical feature" involving an isolated polypeptide comprising a member selected from the group consisting of an amino acid sequence matching to SEQ.ID.NO: 2 or 4. Although the applicant's above concept may link the two sequences SEQ.ID.NO: 2 or 4, such concept does not constitute a "special technical feature" as defined by PCT Rule 13.2 (37CFR1.475(a)) because these two proteins are different to each other and do not share a common amino acid sequence. Applicant has not shown how these proteins are integrally related, what are those structural elements that are shared by theses sequences and what is the common property. These sequences may share certain motifs and sequence similarity to outer membranes proteins of Neisseria meningitidis, however, the Inventions SEQ ID NO: 2 or 4, are different to each as represented by their amino acids (SEQ.ID.NO: 2 consists 722 amino acids, SEQ.ID.NO: 4 consists of 691etc) and are designated with different sequence identification numbers. The requirement is still deemed proper and is therefore made FINAL.

4. Claims 26, 28, 30, 33, 34, 35, 36 – 42, 45 and 47-49 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Claim 35 is withdrawn from group I as it is drawn to a different invention SEQ ID NO: 4. Claims 25, 27, 29, 31, 32, 43- 44 and 46 with respect to SEQID.NO: 2 are under examination in this application.

Priority

5. This application is a 371 of PCT/EP00/00137, 01/10/2000, which claims priority to foreign application UNITED KINGDOM 9900959.9 01/15/1999 is acknowledged.

The examiner has reviewed Foreign application, UNITED KINGDOM 9900959.9 01/15/1999 and find support for the claimed subject matter, an isolated polypeptide comprising SEQ.ID.NO: 2 (722 amino acids) Accordingly, the subject matter defined in the elected claims, 25, 27, 29, 31, 32, 43- 44 and 46 drawn to SEQ ID NO: 2 ~~have~~ has an effective filing date of 01/15/1999 that of the UNITED KINGDOM 9900959.9.

Drawings

6. The drawings are objected to by the draftsperson under 37 C.F.R. 1.84 or 1.152. See PTO-948 for details.

Information Disclosure Statement

7. The Information Disclosure Statement has not been filed in this application.

Specification - Informalities

8. Applicant should follow the direction or order or arrangement in framing the specification as provided in 37 CFR 1.77(b) since this is a utility application filed in USA.

For example: Claims should begin with "I claim" or "'we claim" or "What is claimed is".

It is noted that Abstract of the Disclosure is missing. If applicant desires to include the abstract from the PCT/EP00/00137, , a copy of the abstract will be inserted in to the specification.

There are no line numbers in the specification pages.

No Brief Description of Drawing is present in the application.

Applicant is advised to restrict the claims 25, 27, 29, 31, 32, 43- 44 and 46 to SEQID.NO: 2 since this is an elected invention.

Claim Rejections - 35 USC 112, first paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 25, 27, 29, 31, 32, 43- 44 and 46 are rejected under 35 U.5.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the interim guidelines on written description published June 15, 1998 in the Federal Register at Volume 63, Number 114, pp 32639-32645 (also available at www.uspto.gov). This is a written description rejection.

The specification describes the polypeptide SEQ ID NO: 2, (see page 1-9) from Neisseria meningitidis comprising 722 amino acids. The actual biological function of the polypeptide, SEQ ID NO: 2 is not set forth in the specification. Applicants broadly describe the fragments of SEQ.ID.NO: 2 obtained by embracing any substitution, insertion or deletion of amino acid throughout the entire stretch of polypeptide by use of language in which a fragment

sequence of 15 amino acids or 20 amino acids that matches an aligned contiguous segment of SEQ.ID.NO: 2. None of these fragments meets the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she] invented what is claimed." (See Vas-Cath at page 1116.).

The specification fails to teach a single fragment of a polypeptide sequence of SEQ ID NO: 2 and it is noted that the claimed polypeptides do not exist as an invention independent of their function in a putative outer membrane polypeptide. The actual structure or other relevant identifying characteristics of each fragment having the claimed properties of the polypeptide can only be determined empirically by actually making every amino acid which can result in fragments with 15 or 20 amino acids and testing each to determine whether it is a polypeptide having the particularly disclosed properties of an BASB053 polypeptide.

There must be some nexus between the structure of the polypeptide fragments and the function of that fragment. The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of a representative number of polypeptides, sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. With the exception of an isolated polypeptide comprising SEQ ID NO: 2, fragments comprising 15 or 20 amino acids the skilled artisan cannot envision the contemplated sequences by the detailed chemical structure of the claimed fragments regardless of the complexity or simplicity of the art. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential

method for making it. See Fiers v. Revel, 25 U5PQ2d 1601, 1606 (CAFC 1993) and Amgen Inc V Chuaai Pharmaceutical Co Ltd., 18 U5PQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 U5PQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

10. Claims 25, 27, 29, 31, 32, 43- 44 and 46 are rejected under 35 U.5.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising the amino acid sequence SEQ ID NO: 2 and a fusion protein comprising the amino acid sequence as set forth in SEQ.ID.NO: 2 and an heterologous amino acid sequence, the specification does not reasonably provide enablement for any immunogenic polypeptide comprising a fragment sequence of at least 15 or 20 amino acids that matches contiguous segment of SEQ.ID.NO: 2 or vaccines comprising SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Instant claims are evaluated for enablement using Wands analysis. Many of the factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The specification fails to indicate the biological activity of SEQ ID NO: 2, fails to teach that SEQ ID NO: 2, a polypeptide that is detected by immune or convalescent sera and further lacks any description of polypeptide SEQ ID NO: 2 which acts as a vaccine comprising a

fragment sequence of at least 15 or 20 amino acids that matches contiguous segment of SEQ.ID.NO: 2. The specification is not enabled for any immunogenic polypeptide comprising a fragment sequence of at least 15 or 20 amino acids that matches contiguous segment of SEQ.ID.NO: 2, because 1) the specification fails to teach that the alleged polypeptide SEQ ID NO: 2 is able to function as a vaccine 2) the specification fails to teach how to make and use fragments thereof that have an unknown and uncharacterized function; 3) the specification fails to teach what are the critical residues that can be modified and still achieve a fragment with any functional activity or any fragments with vaccine characteristics for Neisseria meningitidis, - 4) the art teaches that polypeptides with replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition, one skilled in the art would have reason to doubt the validity and functionality of the function of the polypeptide of SEQ ID NO:2 as a vaccine or use of fragments thereof and 5) applicants have not displayed a nexus between the structure of the amino acid sequence SEQ.ID.NO: 2 and function of the polypeptide as a vaccine.

As to points 1)- 5), the specification fails to provide a written description of any immunogenic polypeptide comprising a fragment sequence of at least 15 or 20 amino acids that matches contiguous segment of SEQ.ID.NO: 2 or a polypeptide comprising the disclosed SEQ ID NO: 2 is able to be used as a vaccine. The specification fails to teach the critical polypeptide residues involved in the function of the polypeptide SEQ ID NO: 2, such that the skilled artisan is provided no guidance to test, screen or make fragments of the polypeptide comprising SEQ ID NO: 2 or the polypeptide comprising SEQ ID NO: 2, using conventional technology which allow for a vaccine use in the specification. The specification fails to teach to what extent one could alter SEQ ID NO: 2 and still present the sequence as a vaccine. The specification also fails to demonstrate the actual biological function of the polypeptide and only assigns it as a

polypeptide. Even if one were to use the in vivo vaccine methodology of the specification to screen for a vaccine, one of skill in the art would be reduced to merely randomly altering amino acid(s), which would lead to unpredictable results regarding the functional activity of the polypeptide to be used as a vaccine. Moreover, polypeptide chemistry is probably one of the most unpredictable areas of biotechnology and the art teaches that the significance of any particular amino acid and sequences for different aspects of biological activity can not be predicted a priori and must be determined empirically on a case by case basis (Rudinger et al, in "PEPTIDE HORMONES", edited by Parsons, J.A., University Park Press, June 1976, page 6). The art specifically teaches that even a single amino acid change in a polypeptide leads to unpredictable changes in the biological activity of the polypeptide. For example, replacement of a single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological-activity of the polypeptide (Burgess et al., The Journal of Cell Biology, 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine, or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biologic activity of the mitogen (Lazar et al., Molecular and Cellular Biology, 8(3): 1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of a polypeptide. Polypeptides with replacement of a single amino acid residue may lead to both structural and functional changes in biological activity and immunological recognition. For example, Jobling et al. (Mol. Microbiol. 1991, 5(7): 1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which products polypeptides that differ in native conformation, immunological recognition, binding and toxicity, thus exemplifying the importance of structural components to both biological function and

immunological recognition. Applicants have not taught which residues of SEQ ID NO: 2 can be varied and still achieve a polypeptide that is functional as a vaccine. The specification has not conceived any other functionally equivalent polypeptide fragment and does not set forth the general tolerance to substitutions and where substitutions could be made. Since, the specification lacks a written description of any immunogenic polypeptide comprising a fragment sequence of at least 15 or 20 amino acids that matches contiguous segment of SEQ.ID.NO: 2 it is not enabled for this language because it fails to enable the skilled artisan to envision the detailed chemical structure of the claimed polypeptide fragments of SEQ ID NO: 2 as well as how to use the polypeptide fragments, one of skill in the art would be unable to produce these polypeptide fragments encompassed by the instant claims. Further, if one nucleotide is deleted or inserted at a single place within the coding sequence, all the codons down stream of that insertion or deletion will be frame shifted. The lack of enabling description of make and use a polypeptide comprising a fragment sequence of at least 15 or 20 amino acids that matches contiguous segment of SEQ.ID.NO: 2, the unpredictability associated with making and using the fragments of SEQ ID NO: 2 encompassed in the scope of the claims as set forth above, the lack of teaching even a beginning point for variation of the polypeptide sequence of SEQ ID NO: 2 for routine experimentation, lack of working examples commensurate in scope with the instant claims, the skilled artisan would be forced into undue experimentation to practice (i.e. make and use) the invention as is broadly claimed.

11. Claims 43-44 are drawn to a vaccine compositions. The specification provides no information on the immunogenicity of polypeptide SEQ.ID.NO: 2, the claimed fragments or the ability of such to protect from disease. The specification fails to teach that the claimed polypeptide, SEQ.ID.NO: 2 or fragments are capable of generating a humoral or cellular immune response. The specification also fails to teach that the immune/antibody response to

the polypeptide produced by the polypeptide comprising an amino acid sequence as set forth in SEQ.ID.NO: 2, alone or in combination with adjuvant or carriers provides for a protection against infection in any acceptable animal model. Vaccines by definition trigger an immunoprotective response in the host vaccinated and mere antigenic response is insufficient to provide for enablement of vaccines. This specification fails to teach any immune response generated by means of a nucleic acid --vaccine. It is well recognized in the vaccine art, that it is unclear whether an antigen(s) derived from a pathogen will elicit protective immunity. Ellis, R.W. (Chapter 29 of "VACCINES" [Plotkin, 5.A. et al. (eds) published by W. B. Saunders company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that polypeptide component of a virus or microbial pathogen that itself can elicit the production of protective antibodies.... and thus protect the host against attack by the pathogen". The specification fails to teach even one of the claimed polypeptide or fragments thereof alone or in combination with other antigens does in fact confer protection from infection, as is requisite of a vaccine composition. The art teaches that the selection of protective antigens from the plethora of polypeptide antigens available is unpredictable. While the specification teaches the polypeptide, the art does not recognize the claimed polypeptide or fragments thereof as therapeutic vaccines capable of conferring protection against N.meningitidis challenge in an immunized host.

The specification fails to teach that the claimed polypeptide or fragment is able to perform as a vaccine (i.e. protection, reduction in morbidity and/or mortality of disease) and the art does not recognize other similar polypeptides as operative vaccines. The courts have held that it is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute adequate enablement. (Genentech Inc. v. Novo

Nordisk A/5 Ltd., 42 USPQ2d 1001). Moreover, the specification must have been enabling at the time the invention was made-and developments after the time of filing are of no consequence to what one skilled in the art would have believed at the time of filing (In re Wright, 27 U5PQ2d 1510).

The specification discloses (pages 55-56) that the polypeptide of the instant claims are intended for use as "vaccine" composition" "useful for preventing meningococcal infections." The specification, however, provides no working examples demonstrating (i.e., guidance) enablement for any *in vivo* uses of the claimed polypeptide. The induction of protective immune response (i.e., bactericidal and protective antibody response) to a meningococcal polypeptide or polysaccharide is complex and unpredictable against all meningococcal serogroups, serotypes and serosubtypes (see abstract of Biotecnologia Aplicada 1996, Vol 13, 1-7. The target antigen, an isolated polypeptide SEQ.ID.NO: 2 has not been shown to elicit an antibody response. Furthermore, it is unclear whether the claimed polypeptide elicits effective (i.e., protective) antibodies that are bactericidal (in vitro) and protective (in vivo) against any serogroup. Thus, an isolated polypeptide, SEQ.ID.NO: 2 as a vaccine composition in the treatment or prevention of meningococcal infections must be considered highly unpredictable, requiring a specific demonstration of efficacy of the polypeptide in any animal model.

In the absence of a teaching of the claimed polypeptide can generate an immune response and that immune response is effective in prevention of disease, the specification is not be enabled for vaccines. In view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

Claim Rejections - 35 USC 112, second paragraph

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 25, 27, 29, 31, 32, 43- 44 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is rejected as being vague and indefinite for the recitation of "matching----." As written it is impossible to understand whether applicant is claiming an isolated polypeptide comprising from the group consisting of an amino acid sequence that matches with the complete sequence as recited in the SEQ.ID.NO: 2 or something less?

Claim 44 is rejected for the recitation of " one other N.meningitidis antigen". It is difficult to understand the metes and bounds of one other antigen as written because claim 25 does not recite the source of the polypeptide.

As to claims 25, 27, 29, 31, 32, 43- 44 and 46, the claim is indefinite as depending upon a non-elected claim or subject matter. Correction is required.

Applicant is advised to restrict the claims to recite only SEQ.ID.NO: 2 since this is an elected invention.

Claim Rejections - 35 USC 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

((b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 25, 27, 29, 31, 32, 43- 44 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al 1997 (J.Ex.Med. Volume 185, Number 7, April 7, 1997 1173-1184).

Claims are directed to an isolated polypeptide or vaccine comprising an amino acid sequence matching amino acid sequence SEQ.ID.NO: 2. Claims are also drawn to a method of inducing an immune response comprising administration of said polypeptide.

Martin et al disclose an isolated polypeptide, outer membrane polypeptide from whole cell lysate of OM preparations from various clinical isolates including nine meningococcal strains two of serogroup A (604A and Z4063), one of serogroup B (608B [B: 2a:P1.2: L3]), two of serogroup C (2241C and 59C), one of serogroup 29-E, one of serogroup W-135, one of serogroup Y (SLATY) and one of serogroup Z (SLATZ) (page 1174, under materials and method, antigens). Monoclonal antibodies were produced by immunizing mice with OM preparation indicating that the disclosed isolated polypeptides are immunogenic and thus read on claim 46. Applicant's use of the open-ended term "comprising " in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Whole cell lysates prepared in buffer (pharmaceutical carrier) from N.meningitidis inherently comprise the amino acid sequence as set forth in the SEQ.ID.NO: 2 and several N.meningitidis antigens. *See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948).* In the absence of evidence to the contrary the claimed isolated polypeptide comprising SEQ.ID.NO: 2 is inherent in the preparations of the disclosed prior art polypeptide. Since the Office does not have the facilities for examining and comparing applicants' claimed isolated polypeptide comprising SEQ.ID.NO: 2, with the polypeptide of prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. *See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.*

It is acknowledged that weight is given to every term in claims 43-44. This is why the instant claims drawn to immunogenic composition i.e., vaccine is scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term vaccine must be weighed with the structural limitations of the claim. Therefore, the examiner is considering vaccine composition as an isolated polypeptide comprising SEQ.ID.NO: 2. If the immunogenic composition i.e., vaccine merely comprises a known composition (i.e., an isolated polypeptide), the term carries little weight absent evidence of structural difference. Of course, the existence of an unobvious structural difference would define over the prior art. Therefore, Martin et al meet the immunogenic/vaccine composition limitation of the claims 43-44. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Status of Claims

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

3/10/03

LF3

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